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10/573,289	02/20/2007	Atsushi Muraguchi	2870-0330PUS1	9388

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EXAMINER

HOBBS, MICHAEL L

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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03/11/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/573,289	Applicant(s) MURAGUCHI ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-26 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 11/05/2009 has been considered and entered for the record.

Preliminary Remarks

2. The following are the examiner's preliminary remarks regarding the Office Action mailed on 08/05/2009 in light of the amendment and remarks filed on 11/05/2009:

Applicant's amendment overcomes the objection to the specification in paragraph 7 of the previous Office Action.

Applicant's amendment overcomes the 35 USC 102(b) rejection in paragraph 9 of the previous Office Action.

3. This application contains claims 1-22 drawn to an invention nonelected with traverse in the reply filed on 08/26/2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Claims 23-26 and 28-31 are pending further examination upon the merits.

Priority

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by Reed et al. (US 2005/0220675 A1).

8. The newly applied reference of Reed qualifies as prior art since it is a continuation-in-part of US Patent Application 10/944,691 filed September 17, 2004 which is a continuation-in-part of US Patent Application 10/913,601 filed on August 5, 2004. US Patent Application 10/913,601 claims priority back to US Provisional Application 60/504,500 filed September 19, 2003 and which contains the feature relied upon for the current rejection.

9. Reed discloses an apparatus for filling a micro-plate where the micro-plate can be made, at least partially, from silicon and includes a hydrophobic coating. For claim 21, the applied reference of Reed discloses that the micro-plate (plate 20) can be treated with a hydrophobic coating such as a fluorocarbon ([0499]) where this coating is being interpreted as around the wells. The coating of the applied reference provides the advantage of reducing the number of water molecules that compete with the seal of the cover ([0499]).

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10. Therefore, Reed meets the limitations of claim 31.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 23-26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatia et al. (US 2002/0072116) in view of Griffith et al. (US 6,197,575 B1).

15. Bhatia discloses nano-porous silicon bioreactor that for claim 23 includes silicon substrate that has been manufactured with micro-pores or micro-wells ([0024]) where the micro-pores are on the scale of or "sized and shaped" to hold an individual hepatocyte ([0024]).

16. While Bhatia discloses a silicon surface that has been oxidized ([0026]) and is therefore, hydrophobic, the reference differs from the instant claim regarding the surface being a fluorocarbon.

17. Griffith discloses a vascularized perfused micro-tissue array that for claim 23 uses a fluorocarbon to cover the channels within the array (col. 11 lines 36-40). This polymer is formed by using etch gasses that react with the exposed Si etchant surfaces to form a fluorocarbon oligomeric/polymeric species such as $C(HF)_x C(F_2)_y C(H_2)_z$ where this polymer is hydrophobic in character (col. 11 lines 46-47). Therefore, it would have been obvious for one of ordinary skill in the art to employ the fluorocarbon polymer coating suggested by Griffith within the wells of Bhatia in order to form a hydrophobic layer within the well. The suggestion for doing so at the time would have been in order to have a hydrophobic layer that allows for cell adhesion to the walls of the channel or

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well to be tailored by the adsorption of extra-cellular matrix proteins (col. 11 lines 50-54).

18. Regarding claim 24, the well shapes based on a wet etching process would have an inverted square pyramidal shape ([0053]). Regarding claim 26, the cell to be cultured is a lymphocyte ([0024]) and the micro-pores of Bhatia are fully capable of being used to detect a single antigen-specific lymphocyte.

19. For claim 28, the micro-well is fully capable of holding a single cell. With regards to claims 29 and 30, the top of the substrate of Bhatia is made of silicon which has the intrinsic property of being hydrophobic and therefore forms a hydrophobic region around the micro-pores.

20. Regarding claim 25, Bhatia discloses that the shape of the wells can be circular ([0024]) and the diameter can range for 10-35 micron for a single hepatocyte up to 50-200 micron for a cluster of cells ([0024]). While Bhatia does not explicitly disclose a well depth, the reference discloses that well depth can be controlled with the proper conditions ([0055]) in the etching process. This implies that the well depth is modified based on the type of cell to be placed within in the micro-pore. Barring any alleged unexpected results, it would be obvious to one of ordinary skill in the art to adjust the well depth in order to hold a single cell of the result effective variable in this known process, consult *In re Boesh and Slaney* (205 USPW 215 (CCPA 1980)).

Response to Arguments

21. Applicant's arguments with respect to claims 23-26 and 28-31 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection are in view of Griffith which discloses a fluorocarbon coating on the channels within an array and Reed which discloses coating the top of a micro-titer plate with a fluorine surface.

Conclusion

22. No claims are allowed.

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Brown et al. (US 2003/0017349 A1) discloses a fluorination process ([0008]) that replaces a superficial hydrogen with a fluorine through a chemical process or by plasma polymerization of fluorine containing gases to create a laboratory equipment with a hydrophobic surface.

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797